REMARKS

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Reconsideration of the present application in view of the following remarks is respectfully requested. The application includes claims 72-135 and 249-361, pending and under consideration.

New claims 249-361 are being added via this Amendment. With the exception of one minor change to correct a clerical error in prior claim 156 (new claim 269) claims 249-361 are the same as previously-cancelled claims 136-248. The Applicant notes that prior claims 136-248 and new claims 249-361 have been copied from U.S. Patent Application No. 10/112,745 to Michelson (U.S. Patent Application Publication No. 2002/0161442) to preserve the Assignee's right to provoke an interference under 35 U.S.C. §135. The Applicant respectfully requests consideration and allowance of the subject application including now pending claims 72-135 and 249-361.

In Applicant's previously-submitted responses dated January 17, 2006, and May 16, 2006, Applicant pointed out distinctions that are believed to render claims 135 and 249-361 (corresponding to prior claims 136-248) patentable over any of the applied references. Applicant also pointed out support for these claims in the specification. That information provided by Applicant is incorporated herein by reference and is believed to satisfy the Examiner's prior request for information.

In the outstanding Action, claims 72-135 were pending, and claims 72-135 stand rejected. In addition, the "amendment filed 12/17/04" is objected to under 35 U.S.C. §132 on

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the grounds that it introduces new matter into the disclosure. Reconsideration of the present application in view of the remarks set forth herein is respectfully requested. For the reasons set forth below, Applicant submits that, and respectfully requests an indication that, each of pending claims 72-135 and 249-361 is in condition for allowance.

As an initial matter, Applicant would draw the Examiner's attention to the amendment to page 1 of the specification, presented above. The purpose of the amendment is to correct a clerical error in the way in which the filing date for United States Patent Application Serial No. 10/035,074 was presented, and to add an "S" to the word "APPLICATION" in the caption.

Turning now to the art rejections asserted in the Action, claims 72-90, 134 and 135 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,258,125 to Paul et al. (hereafter, "the '125 patent") and claims 91-133 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '125 patent in view of U.S. Patent No. 6,530,955 to Boyle et al. (hereafter "the '955 patent").

In traversal of the art rejections, Applicant submits that neither of the references asserted in the Action qualifies as prior art to the pending claims under 35 U.S.C. § 102(e) or any other statutory provision. In this regard, Applicant would draw the Examiner's attention to the follow items of information:

- (1) the '125 patent was filed on July 30, 1999, and claims priority to a provisional patent application file August 3, 1998;
- (2) the '955 patent was filed on May 18, 2001 and is a divisional of a patent application filed June 8, 1999; and

(3) the present application is a continuation application that claims priority to a string of prior patent applications in a line of cases extending back to a parent application filed June 3, 1997 (U.S. Patent Application Serial No. 08/867,963).

In view of the above, the pending claims of the present application are entitled to an effective filing date at least as early as June 3, 1997, for purposes of determining qualification of references as prior art. Neither the '125 patent nor the provisional patent application to which it claims priority was filed before June 3, 1997, and the '125 patent does not qualify as prior art to the present application under 35 U.S.C. § 102(e). Similarly, neither the '955 patent nor the prior patent application to which it claims priority was filed before June 3, 1997, and the '955 patent likewise does not qualify as prior art to the present application under 35 U.S.C. § 102(e).

Consequently, Applicant respectfully requests withdraw of the rejection of claims 72-90, 134 and 135 under 35 U.S.C. § 102(e) as being anticipated by the '125 patent and the rejection of claims 91-133 under 35 U.S.C. § 103(a) as being unpatentable over the '125 patent in view of the '955 patent.

In addition to the above, claims 72-134 are rejected in the outstanding Action under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In support of this rejection, the Action asserts that the specification does not support the recitation in claims 72, 91 and 111 of "...said upper and lower portions being non-arcuate along at least a portion of the length of the implant..." In traversal of this rejection, Applicant submits that a person of ordinary skill in the art at the time of the present application would have understood, based upon the originally-filed specification, that

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Applicant was in possession of the claimed subject matter. For example, the specification describes a modification to the embodiment depicted in Figs. 4 and 5 whereby the upper and lower portions are flattened. This embodiment with flattened upper and lower portions is itself an embodiment in which upper and lower portions are non-arcuate along at least a portion of the length of the implant. Applicant would draw the Examiner's attention to paragraph 78 of the published application (Application Publication No. 2004/0073309),

In some embodiments, the wall 506 may include upper and lower flattened portions to stabilize the dowel by neutralizing any rotational torque that may be induced by pressure on the sidewall. This could be achieved by reducing the height H of the sidewall 505 and ends 501, 502 by filing or like means.

In view of the description in the specification of an embodiment as depicted in Figs. 4 and 5, but with upper and lower flattened portions, Applicant submits that the specification provides solid written description support for the subject matter recited in the pending claims under 35 U.S.C. § 112, first paragraph. Applicant therefore respectfully requests withdrawal of this rejection.

At page 4 of the Action the Examiner makes an analogy to a road having a flattened surface and that curves to the left or right, and states that such a road would be considered flattened and arcuate. In reply, Applicant submits that the existence of alternative embodiments that are not representative of a subject claim is not a valid reason to reject a claim under Section 112, first paragraph. The specification clearly describes an embodiment having upper and lower portions that are non-arcuate along at least a portion of the length of

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which states the following:

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the implant, and this claim therefore satisfies the written description requirement of Section 112, first paragraph. Moreover, Applicant submits that a spacer having a flattened side and that bends along its length would also be understood by a person skilled in the art at the time of the present application to be contemplated by the wording "said upper and lower portions being non-arcuate along at least a portion of the length of said implant."

The outstanding Action also includes a new matter objection, and an accompanying rejection under Section 112, first paragraph, with regard to the amendment filed 12/17/04 in which the following language was inserted into the specification: "Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body." In support of the objection and rejection, the Examiner cites MPEP 2125 in support of the proposition that, "proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale."

In traversal of the new matter objection and rejection, applicant submits that the identified subject matter would have been understood by a person of ordinary skill in the art at the time of the application to be reasonably taught by the descriptions provided in the application, and does not rely upon proportions depicted in the drawing. As such, the identified subject matter does not constitute new matter. In this regard, Applicant notes that MPEP 2125 also states that, "the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art." (citation omitted). In the present case, the subject claims are directed to an "interbody spinal implant." The term "interbody" is understood by skilled artisans to mean

RESPONSE TO OFFICE ACTION Serial No. 10/699,175 Attorney Docket No. MSDI-434 Page 39 of 42 located between the bodies of two adjacent vertebra. Paragraph 66 of the published version of the present application (Application Publication No. 2004/0073309) includes the following statement regarding the embodiment depicted in Fig. 6: "Bilateral placement of dowels 500 is preferred as shown in FIG. 6." The term "bilateral" is well understood by skilled artisans to mean located on two sides of an axis. More specifically, in terms of interbody spinal implants, the term "bilateral" is understood to mean located on two sides of the central axis of the spinal column. Moreover, dowels 500 depicted in Fig. 6 do not overlap one another or cross the central axis of the vertebrae. Therefore, Fig. 6, which depicts an embodiment of the application involving bilateral placement of two dowels for operation as an interbody spinal implant, would be clearly understood to be characterized by each dowel having a width less than approximately one-half of the width of the adjacent vertebral body. This is the case irrespective of the sizes of the vertebral bodies, or the size proportions between the vertebral bodies and the spacers. Otherwise, the dowels could not be both bilateral and positioned between vertebral bodies. Applicant acknowledges the statement in the Action that, "it would be possible to place larger implants in the space that would overlap allowing for a width greater than half of the vertebral bodies width." In reply, Applicant would again note that the proper inquiry under Section 112, first paragraph, is whether the specification describes the identified subject matter, not whether alternative embodiments might exist that differ from an exemplary embodiment specifically shown and described in the specification and recited in a given claim. A person skilled in the art at the time the application was filed would have understood, based upon the drawings and the

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accompanying descriptions, that the embodiment depicted in Fig. 6 includes two dowels that each has a width less than approximately one-half of the width of the adjacent vertebral body.

In view of the above, Applicant submits that support for the identified statement is clearly present in the application as filed, and does not rely upon any proportions of elements shown in a drawing. Applicant therefore respectfully requests that the objection to the specification and the rejection of claims based upon the identified specification amendment be withdrawn.

In view of the foregoing remarks, Applicants respectfully submit that none of the rejections asserted in the Action can properly be maintained. Accordingly, reconsideration leading to withdraw of all the rejections and allowance of this application containing claims 72-135 and 249-361 are respectfully requested.



In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

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